



Australian Government

Australian Government response to the Senate Rural and
Regional Affairs and Transport Legislation Committee
inquiry report:

Agricultural and Veterinary Chemicals Legislation
Amendment (Streamlining Regulation) Bill 2018 [Provisions]

April 2019

INTRODUCTION

On 29 November 2018, the Senate Selection of Bills Committee referred the provisions of the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (the Bill) to the Senate Rural and Regional Affairs and Transport Legislation Committee (the Committee) for inquiry and report by 11 February 2019.

The Committee examined:

- the impact of the bill on the regulation of agricultural and veterinary medicines products in Australia
- amendments to the
 - *Agricultural and Veterinary Chemicals (Administration) Act 1992*
 - *Agricultural and Veterinary Chemicals Code Act 1994*
 - *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*
- the impact of the bill on agricultural industries and other relevant stakeholders.

The Committee published its report on 11 February 2019 with one recommendation; that the Bill be passed. The Committee highlighted that the evidence it received during the inquiry indicated broad stakeholder support for the Bill and its intent to improve the effectiveness of agvet chemical regulation in Australia.

The Australian Labor Party and the Australian Greens Committee members provided dissenting reports.

The government provides the following response.

DETAILED RESPONSE TO THE RECOMMENDATIONS OF THE MAJORITY REPORT

RECOMMENDATION 1

The Committee recommends the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 be passed.

The Australian Government welcomes and agrees with the Committee's recommendation that the Bill should be passed.

Streamlining the regulation of agricultural and veterinary (agvet) chemicals was a government commitment made in the 2015 *Agricultural Competitiveness White Paper* (the White Paper). The government remains committed to delivering the White Paper initiatives.

DETAILED RESPONSE TO THE AUSTRALIAN LABOR PARTY'S DISSENTING REPORT

RECOMMENDATION 1

The Australian Labor Party recommends that the Government remove the Part 5—Accreditation of Assessors measure.

The Australian Government does not support the recommendation.

The government first discussed the accredited assessor measure with stakeholders during consultations in 2015 and it is a commitment in the White Paper. A similar accreditation scheme exists for veterinarians in the *Export Control Act 1982* and New Zealand also utilises an accredited assessor scheme as part of its registration system.

Importantly, the APVMA already can, and does, utilise external assessor arrangements. For example, the APVMA directly engages external assessors to evaluate various components of the applications submitted to it (e.g. environment or efficacy). Additionally, the APVMA has operated an administrative scheme—that commenced in 2016—for pre-application assessment services for efficacy and target crop/animal safety. This involves applicants engaging an external assessor from a list of potential assessors selected by the APVMA. The proposed measure in Part 1 of the Bill would improve the transparency of this process and provide for parliamentary oversight.

Conflict of Interest

The proposed model includes appropriate safeguards to respond to potential issues within the accreditation scheme, such as perceived or actual conflicts of interest. Under the proposed measure, regulation may prescribe penalties for offences, as well as providing for civil proceedings, should an accredited person contravene a condition of accreditation or other requirement. The ability to prescribe offences and civil penalty provisions will ensure that the Australian Pesticides and Veterinary Medicines Authority (APVMA) can respond proportionately to situations that may arise. These sanctions would be in addition to administrative sanctions, such as suspension or cancellation of accreditation for assessors, which are also available to the APVMA.

Most importantly however, the measure does not provide for the APVMA to delegate any of its powers to an external assessor. The legislation will continue to require that the APVMA remains the decision maker in all cases for active constituent and label approvals, and product registrations.

Liability Limitations for Assessors

Providing liability limitations or waivers for assessors in the legislation may create an incentive for, or remove a potential barrier that prevents assessors operating beyond their area of expertise or preparing poor quality work. This may compromise the integrity of Australia's agvet chemical regulatory framework.

Furthermore, the government considers that professional indemnity insurance would be a more appropriate means for assessors to reduce their potential liability risk rather than transferring this risk and the associated costs to Australian taxpayers.

DETAILED RESPONSE TO THE AUSTRALIAN GREENS' DISSENTING REPORT

RECOMMENDATION 1

The Australian Greens recommend that the Bill be opposed.

The Australian Government does not support the recommendation.

The government recognises the need to better balance regulatory effort with risk and improve farmers' and other users' access to newer and better agvet chemicals.

As part of the White Paper, the government committed to a \$17.1 million measure over four years to improve access to agvet chemicals, while retaining protections for the health and safety of humans, animals, plants and the environment, and Australia's trade.

Accreditation of Assessors (Schedule 1, Part 5)

Conflict of Interest

The government's response to the Australian Greens' concerns about the potential conflict of interest that this measure could create is the same as provided in reply to the Australian Labor Party's recommendation above.

Parliamentary Oversight – Disallowable Legislative Instrument

The measure will provide for a scheme designed and detailed by the APVMA in a disallowable legislative instrument.

While the government has confidence in the APVMA to design and administer the accredited assessor scheme, the government recognises the importance of parliamentary oversight. This is why the scheme is to be set out in a disallowable legislative instrument. It will enable parliament the ability to scrutinise (e.g. via the Senate Standing Committee on Regulations and Ordinances) the legislative instrument the APVMA prepares for the scheme. This will improve the transparency and accountability of the APVMA's existing administrative arrangements for external assessors.

Approval and Registration for Prescribed Active Constituents, Chemical Products or Labels (Schedule 1, Part 1)

The measure proposed is not a new concept for agvet chemical legislation. Under Part 2 of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, processes already exist that provide for variations with reduced information requirements and lighter-touch 'assessments', where the risks associated with a variation warrant such an approach.

The proposed measure simply extends this mechanism by amending the agvet legislation to provide the APVMA with greater flexibility to manage applications and better align regulatory effort with risk, similar to its existing pathway for prescribed variations.

The government is confident about the judgment and expertise of the APVMA staff (as they currently exercise it for notifiable and prescribed variations), in identifying which products are considered low risk and are therefore suitable for the proposed prescribed pathway.

Limits on Use of Information (Schedule 1, Part 3)

This measure will provide incentives for the agvet chemicals industry to seek approval of certain kinds of active constituents with new, desirable features (such as new modes of action to manage

resistance) or to register certain uses (such as minor uses) of chemical products. This will provide growers and other users with access to new, safe chemistries that they would not otherwise have.